

ADVIL COLD AND SINUS- ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

ACTIVE INGREDIENTS (IN EACH LIQUID-FILLED CAPSULE)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

Pseudoephedrine HCl 30 mg

*nonsteroidal anti-inflammatory drug

PURPOSES

Pain reliever/fever reducer

Nasal decongestant

USES

temporarily relieves these symptoms associated with the common cold or flu:

- headache
- fever
- sinus pressure
- nasal congestion
- minor body aches and pains

WARNINGS

Allergy alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- in children under 12 years of age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other product that contains pseudoephedrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better

- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years of age and over:
 - take 1 capsule every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 capsule, 2 capsules may be used.
 - do not use more than 6 capsules in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use

OTHER INFORMATION

- each capsule contains: **potassium 20 mg**
- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

INACTIVE INGREDIENTS

D&C yellow no. 10, FD&C red no. 40, gelatin, medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

QUESTIONS OR COMMENTS?

Call weekdays **9 AM to 5 PM EST** toll free at **1-800-88-ADVIL**

PRINCIPAL DISPLAY PANEL

Advil®

COLD & SINUS Non-Drowsy

Ibuprofen 200 mg □ Pain Reliever/Fever Reducer (**NSAID**)

Pseudoephedrine HCl 30 mg □ Nasal Decongestant

**Relieves Sinus Pressure,
Nasal Congestion and Fever**

***LIQUI-GELS*®**

32 LIQUID-FILLED CAPSULES

LIQUID-GELS®
COLD & SWEET

APV

QUESTIONS OR COMMENTS? CALL 800-86-ADVERT OR VISIT www.800-86-ADVERT.COM

Inactive ingredients: DSC yellow no. 10; FD&C red no. 40; glycol, polyvinylpyrrolidone, purified water, sorbitol solution, sodium lauryl sulfate, medium-chain triglycerides, pharmaceutical grade polyethylene glycol.

Drug Facts (continued)

(continued) *see* p. 10

- do not use more than listed
- the smallest effective dose should be used
- adults and children 12 years of age and over:
 - take 1 capsule every 6 to 8 hours while symptoms persist.
 - if symptoms do not respond to 1 capsule, 2 capsules may be used.
- do not use more than 6 capsules in any 24-hour period
- adults divided by a doctor
- children under 12 years of age do not use

Directions

• **Check for drug interactions.** Taking any other drug decreases the benefit of aspirin. Taking aspirin for heart attack or stroke, because aspirin may raise the blood sugar level, may increase the risk of complications if you are taking any other product that contains pseudoephedrine or any other decongestant.

ask your doctor whether any of the following apply to you:

patient have ever had an allergic reaction to any other
plant or flower product
or if you are now taking a prescription monoamine oxidase inhibitor
(MAOI) (certain drugs for depression, psychotic, or anesthetic
conditions, or Parkinson's disease), or for 2 weeks after stopping
the MAOI drug. If you do not normally use prescription drugs containing
an MAOI, ask a doctor or pharmacist before taking this product.

Heart attack and stroke warning: NSAIDs, especially aspirin, increase the risk of heart attack, heart failure, and stroke. There can be fatal. The risk is higher if you use more than directed or for longer than directed.

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in pregnant or breastfeeding, ask a health professional before use. It is especially important to use Enclonin during the last 3 months of pregnancy unless definitely decided to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

- started again?
- hurted in one part or side of body
- no swelling
- have got a worse or lasts more than 7 days
- have a cough or short later for more than 7 days
- symptoms continue or get worse
- progress or swelling is present in the genital area
- you get dizziness or faints
- any new skin symptoms appear

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - you have symptoms of heart problems or stroke
 - chest pain
 - trouble breathing

When using this product
 ■ take with food or milk if stomach upset occurs

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- minor body aches and pains
- tired or congested
- sinus pressure
- headache ■ fever

Use: Temporarily relieves these symptoms associated with the common cold or flu:

Soluble (approx equal to
in 200 mg (approx 0.5 g)
(present as the free acid and potassium salt)
Sodium chloride (HCl) 30 mg
Nonacidic and inflammatory drug

Drug Facts	Active ingredients	Purposes
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Drug Facts

[illegible]

Drug Facts (continued)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Advil®

COLD & SINUS Non-Drowsy

Ibuprofen 200 mg > Pain Reliever/Fever Reducer (**NSAID**)
Pseudoephedrine HCl 30 mg > Nasal Decongestant

**Relieves Sinus Pressure,
Nasal Congestion and Fever**

LIQUI-GELS®

Advis
CRS

32 LIQUID-FILLED CAPSULES

Advil[®] COLD & SINUS
Liqui-GELS[®]
Relieves Sinus Pressure, Nasal Congestion and Fever

Advil[®] COLD & SINUS
Liqui-GELS[®]

Product inside sealed in plastic blister
with foil backing. Do Not Use if plastic
blister or foil barrier is broken.

For most recent product information,
visit www.advil.com

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PAN081954





ADVIL COLD AND SINUS

ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0184
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	Advil;C;S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0184-32	32 in 1 CARTON	05/30/2002	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0573-0184-16	16 in 1 CARTON	05/30/2002	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021374	05/30/2002	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Registrant - Pfizer Inc (113480771)

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GlaxoSmithKline Consumer Healthcare Holdings (US) LLC